Docket No.: UF-10488R
Serial No.: 10/005,374

In the claims:

1. (original) Biocompatible particles for delivery of a vaccine to the pulmonary system comprising an immunizing agent; wherein the particles have a tap density less than 0.4 g/ml and at least 90% of the particles have geometric dimensions between about 5 μm and about 30 μm.

2. (original) The particles of claim 1 wherein the immunizing agent is selected from the group consisting of a live attenuated virus or bacterial vaccine, a recombinant virus or bacterial vaccine encoding an immunizing antigen or a combination of antigens against which elicitation of an immune response is desired, and an inactivated virus or bacterial vaccine.

3. (currently amended) The particles of claim 1 combined with large biodegradable carrier particles having a mass mean diameter in the range of about 50 ~~mu.m~~ μm to about 100 ~~mu.m~~ μm.

4. (original) The particles of claim 1 combined with a pharmaceutically acceptable carrier for administration to the respiratory tract.

5. (currently amended) The particles of claim 1 wherein at least 90% of the particles have a mass mean diameter between about 5 ~~mu.m~~ μm and about 15 ~~mu.m~~ μm.

6. (currently amended) The particles of claim 1 wherein at least 90% of the particles have a mean diameter between about 9 ~~mu.m~~ μm and about 11 ~~mu.m~~ μm.

7. (currently amended) The particles of claim 1 wherein at least 50% of the particles have a tap

density of less than 0.1 ~~g/cm.sup.3~~ g/cm^3.

8. (original) The particles of claim 1 wherein the particles further comprise a polymeric material.

9. (original) The particles of claim 1 wherein the particles further comprise a non-polymeric material.

10. (currently amended) Biocompatible particles for delivery of a targeting molecule to the pulmonary system wherein the targeting molecule is attached to the particles and wherein the particles have a tap density less than 0.4 g/cm~~.sup.3~~ g/cm^3, and at least 90% of the particles have geometric dimensions between 5 ~~.mu.m~~ µm and about 30 ~~.mu.m~~ µm.

11. (currently amended) Biocompatible particles for delivery of a vaccine agent to the pulmonary system comprising an immunologically effective amount of a vaccine agent; wherein the particles have a tap density less than 0.4 ~~g/cm.sup.3~~ g/cm^3 and at least 90% of the particles have an aerodynamic diameter between about 1 ~~.mu.m~~ µm and about 5 ~~.mu.m~~ µm.

12. (original) The particles of claim 11 wherein the agent is selected from the group consisting of viral vaccines, bacterial vaccines, live, attenuated, recombinant, inactivated, and combinations thereof.

13. (currently amended) The particles of claim 11 combined with large biodegradable carrier particles having a mass mean diameter in the range of about 50 ~~.mu.m~~ µm to about 100 ~~.mu.m~~ µm.

14. (original) The particles of claim 11 combined with a pharmaceutically acceptable carrier for administration to the respiratory tract.

15. (currently amended) The particles of claim 11 wherein at least 90% of the particles have an

aerodynamic diameter between about 1 ~~.mu.m~~ μm and about 3 ~~.mu.m~~ μm.

16. (currently amended) The particles of claim 11 wherein at least 90% of the particles have an aerodynamic diameter between about 3 ~~.mu.m~~ μm and about 5 ~~.mu.m~~ μm.

17. (currently amended) The particles of claim 11 wherein at least 50% of the particles have a tap density of less than 0.1 ~~g/cm.sup.3~~ g/cm^3.

18. (original) The particles of claim 11 wherein the particles further comprise a polymeric material.

19. (original) The particles of claim 11 wherein the particles further comprise a non-polymeric material.

20. (currently amended) Biocompatible particles for delivery of a vaccine and targeting molecule to the pulmonary system wherein the targeting molecule is attached to the particles and wherein the particles have a tap density less than 0.4 ~~g/cm.sup.3~~ g/cm^3, and at least 90% of the particles have an aerodynamic diameter between about 1 ~~.mu.m~~ μm and about 5 ~~.mu.m~~ μm.

21. (currently amended) A method for delivery of an actively immunizing amount of a vaccine to the pulmonary system comprising: administering to the respiratory tract of a patient in need thereof of an effective amount of biocompatible particles incorporating said vaccine, wherein the particles have a tap density of less than about 0.4 ~~g/cm.sup.3~~ g/cm^3 and at least 90% of the particles have geometric dimensions between about 5 ~~.mu.m~~ μm and about 30 ~~.mu.m~~ μm.

22. (original) The method of claim 21 wherein the agent is selected from the group consisting of viral vaccines, bacterial vaccines, live, attenuated, recombinant, inactivated, and

combinations thereof.

23. (currently amended) The method of claim 21 wherein the particles are combined with large biodegradable carrier particles having a mass mean diameter in the range of about 50 ~~.mu.m~~ μm to about 100 ~~.mu.m~~ μm.

24. (original) The method of claim 21 wherein the particles are combined with a pharmaceutically acceptable carrier for administration to the respiratory tract.

25. (currently amended) The method of claim 21 wherein at least 90% of the particles have a mass mean diameter between about 5 ~~.mu.m~~ μm and about 15 ~~.mu.m~~ μm.

26. (currently amended) The method of claim 21 for delivery to the alveolar zone of the lung wherein at least 90% of the particles have a mean diameter between about 9 and about 11 ~~.mu.m~~ μm.

27. (currently amended) The method of claim 21 wherein at least 50% of the administered particles have a tap density of less than about 0.1 ~~g/cm.sup.3~~ g/cm^3.

28. The method of claim 21 wherein the particle's further comprise a polymeric material.

29. (original) The method of claim 21 wherein the particles further comprise a non-polymeric material.

30. (currently amended) A method for delivery of a vaccine and a targeting molecule to the pulmonary system comprising: administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of biocompatible particles, wherein the particles have a tap density less than about 0.4 ~~g/cm.sup.3~~ g/cm^3 and at least 90% of the particles

have geometric dimensions between about 5 ~~.mu.m~~ µm and about 30 ~~.mu.m~~ µm, and wherein the targeting molecule is attached to the particles which further comprise the vaccine.

31. (currently amended) A method for delivery of a vaccine to the pulmonary system comprising: administering to the respiratory tract of a patient in need thereof of an effective amount of biocompatible particles comprising said vaccine, wherein the particles have a tap density of less than about 0.4 ~~g/cm.sup.3~~ g/cm^3 and at least 90% of the particles have an aerodynamic diameter between about 1 ~~.mu.m~~ µm and about 5 ~~.mu.m~~ µm.

32. (original) The method of claim 31 wherein the agent is selected from the group consisting of viral vaccines, bacterial vaccines, live, attenuated, recombinant, inactivated, and combinations thereof.

33. (currently amended) The method of claim 31 wherein the particles are combined with large biodegradable carrier particles having a mass mean diameter in the range of about 50 ~~.mu.m~~ µm to about 100 ~~.mu.m~~ µm.

34. (original) The method of claim 31 wherein the particles are combined with a pharmaceutically acceptable carrier for administration to the respiratory tract.

35. (currently amended) The method of claim 31 wherein at least 90% of the particles have an aerodynamic diameter between about 1 ~~.mu.m~~ µm and about 3 ~~.mu.m~~ µm.

36. (currently amended) The method of claim 31 for delivery to the alveolar zone of the lung wherein at least 90% of the particles have an aerodynamic diameter between about 3 ~~.mu.m~~ µm and about 5~~.mu.m~~ µm.

37. (currently amended) The method of claim 31 wherein at least 50% of the administered

particles have a tap density of less than about 0.1 ~~g/cm.sup.3~~ g/cm^3.

38. (original) The method of claim 31 wherein the particles further comprise a polymeric material.

39. (original) The method of claim 31 wherein the particles further comprise a non-polymeric material.

40. (currently amended) A method for delivery of a vaccine and a targeting molecule to the pulmonary system comprising: administering to the respiratory tract of a patient in need of treatment, prophylaxis or diagnosis an effective amount of biocompatible particles comprising said vaccine, wherein the particles have a tap density less than about 0.4 ~~g/cm.sup.3~~ and at least 90% of the particles have an aerodynamic diameter between about 1 ~~.mu.m~~ μm and about 5 ~~.mu.m~~ μm, and wherein the targeting molecule is attached to the particles.